American Journal of Infection Control ■■ (2018) ■■-■■

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

Efficacy of bladder irrigation in preventing urinary tract infections associated with short-term catheterization in comatose patients: A randomized controlled clinical trial

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Key Words:
Coma
intensive care units

Background: Bladder irrigation can be performed to prevent catheter-associated urinary tract infections (CAUTI), but its efficacy has been not reported in short-term indwelling urinary catheterization. This clinical trial aimed to examine the efficacy of bladder irrigation with normal saline solution in preventing CAUTI in comatose patients admitted to intensive care units.

Materials and methods: Eligible patients were randomized to the experimental group or control group. The experimental group received daily bladder irrigation with 450 cc sterile normal saline, in 3 150-mL doses, for 3 consecutive days. Data on signs of CAUTI, including urine culture, axillary body temperature (primary outcomes), and other urine and blood parameters (secondary outcomes) were obtained at baseline and 5 days later.

Results: Results of group comparisons and logistic regression analysis that controlled for fluid intake showed that the risk of CAUTI decreased by 99% in the experimental group compared with the control group (odds ratio, 0.01; $P < .001$). Additional findings indicated a decrease in axillary body temperature and improvements in urine appearance, urinary red cells and white cells, and erythrocyte sedimentation rates and white-cell counts in the blood following bladder irrigation.

Conclusion: Daily bladder irrigation with normal saline during 3 days demonstrated efficacy in preventing CAUTI in comatose patients.

In intensive care units, short-term indwelling urinary catheterization is a fairly routine practice. It is done for 15%-25% of critically ill adult patients[1,2] to monitor urine output and guide fluid resuscitation, as well as to facilitate daily patient care.[3] Catheterization has been shown to increase the risk of catheter-associated urinary tract infections (CAUTIs). CAUTIs are manifested by positive urine culture and at least 1 of these signs and symptoms: fever, suprapubic or costovertebral angle pain or tenderness, urinary urgency, urinary frequency, and dysuria.[4] It is estimated that 97% of UTIs reported in hospitals occurred in catheterized patients.[5] UTIs can develop in less than a week following catheterization and are related to several risk factors. Health care providers' inappropriate

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Supported by the research and technology vice-chancellor at Hamadan University of Medical Sciences. The funding source had no role in the course of study, research, or assembly of the manuscript.
Conflicts of interest: None to report.

0196-6553/
https://doi.org/10.1016/j.ajic.2018.05.009

application of aseptic techniques during catheterization and poor hand hygiene facilitate the transfer of external bacteria into the bladder. Further, less-than-optimal management of the catheter and drainage tube, along with immobility and incomplete bladder emptying in comatose patients[6] may lead to urinary stasis, which provides a favorable medium for bacterial growth. The bacteria colonize the internal lumen of the catheter and form a biofilm,[7] which can lead to CAUTI and catheter blockage.[8] CAUTIs increase the burden of care, length of intensive care and hospital stay, and the cost of care.[9]

Clinical guidelines recommend a range of strategies for reducing the risk of CAUTI associated with long-term indwelling urinary catheterization. Bladder irrigation or washout has been advocated as standard management of long-term catheters.[10] However, a recent Cochrane review[11] found inconclusive evidence to support the effectiveness of bladder irrigation in preventing CATUI. It is plausible that this finding is related to variability in the design and implementation of the irrigation protocol, including the types and volumes of the solution used, the frequency and timing at which the irrigation procedure was done, and the specific techniques applied. There is limited evidence of the influence of bladder irrigation on the prevention of CATUI in critically ill, comatose patients with short-term indwelling urinary catheters. This clinical trial was designed to address this gap in knowledge.

The overall purpose of this clinical trial was to examine the efficacy of bladder irrigation on the prevention of CAUTIs in critically ill, comatose patients catheterized for a short term (<30 days) and receiving care in an intensive care unit. Critically ill patients are often sedated or comatose and unable to report on the symptoms of UTI (eg, pain and dysuria).[12] Therefore, the objective signs of CAUTI were assessed in this trial.

The specific trial objectives were to determine the effects of bladder irrigation on primary outcomes, including urine colony forming units per milliliter and patients' axillary body temperature (°C). Secondary outcomes included urine parameters such as urine specific gravity, pH, white blood cell (WBC) and red blood cell (WBC) deposits, epithelial cells per high power field, and nitrite, as well as blood parameters such as erythrocyte sedimentation rate (ESR), WBCs, and RBCs.

MATERIAL AND METHODS

Design

A prospective, blinded, randomized controlled trial design was used. Eligible patients were randomly assigned to the experimental group or control group as specified by the study group code number written on a card placed in an opaque envelope. Participants in the experimental group received, in addition to usual care, bladder irrigation following the protocol described in a later section, whereas those in the control group were exposed to usual care, which consisted of routine catheter care. Outcome data were collected at the same time points in both groups: time 1, within 48 hours of catheterization (representing baseline), and time 2, 5 days later (representing posttest); CAUTIs can develop with the 5-day time period. Participants' masking was maintained because they were comatose. The outcome assessors and laboratory specialists were blinded to the participants' study group.

The trial was registered the Iranian Registry of Clinical Trials (IRCT201702134578N6). It was conducted according to the principles of the Declaration of Helsinki. The trial protocol was approved by the Research Ethics Committee at Hamadan University of Medical Sciences, Iran (IR.UMSHA.REC.1395.495) and the participating hospital. Because patients were comatose, written informed consent obtained from their family members.

Sample

Patients were eligible if they were aged 18 years or older, were comatose, and had an indwelling urinary catheter within 48 hours before the specimen collection resulted a positive urine culture of $\geq 10^3$ CFU/mL.[13] The exclusion criteria included a history of chronic disease influencing kidney function (eg, diabetes, chronic kidney disease, nephrosclerosis, acute or chronic glomerulonephritis, pyelonephritis, immune deficiency disorders such as lupus erythematosus, rheumatoid arthritis, urethral and/or bladder trauma, current aminoglycoside therapy, and having an infection in other body systems such as respiratory or wound infection). A patient's participation in the trial was terminated if his or her catheter was removed for any reason, or if they were transferred to another hospital unit.

The sample size calculation was informed by the results of a study by Samimi et al[14] that compared the effects of 2 solutions (chlorhexidine and normal saline [NS]) used in bladder irrigations on the prevention of CAUTIs. Based on these results, the probability of a positive urine culture was estimated at 73.2% in the control group (p_1) and at 50% in the experimental group (p_2). Setting the power at 80% and a 2-sided significance level (α) at 0.05, and applying the formula presented below, the number of participants required in each study group was 24. To account for a possible 20% dropout rate over the course of the trial, 30 participants were included in each of the experimental and the control groups, for a total of 60.

$$n = \frac{\left[Z_{1-\frac{\alpha}{2}} \sqrt{p(1-p)} + Z_{1-\beta} \sqrt{p_1(1-p_1) + p_2(1-p_2)} \right]^2}{(p_1 - p_2)^2} \cong 24$$

Over the 7-month trial period (June-December 2017), all patients who were admitted to the participating intensive care unit and were catheterized (n = 139), were screened for eligibility. Of those meeting all eligibility criteria (n = 62), 60 were recruited, and their family members provided written consent.

Treatment protocol

A 3-way indwelling urinary catheter was needed to prevent backflow of urine into the bladder during irrigation.[15] To maintain comparability on catheter type, a 3-way catheter was used for all patients in the control and experimental groups.

Usual care protocol

At the participating intensive care unit, usual care included routine catheter care, as described in clinical practice guidelines. It involved performing hand hygiene, wearing sterile gloves, maintaining an uncontaminated area, using an aseptic technique and sterile insertion technique, securing catheter to the patients' thighs with adhesive tape and below the level of the bladder, regularly emptying the collecting bag, and changing indwelling catheters and the drainage bags every 3 days or based on clinical indications such as infection, obstruction, or leakage.

Bladder irrigation protocol

In addition to usual care, participants in the experimental group received the bladder irrigation protocol, which involved these steps. Skilled aseptic techniques were adhered to when inserting the catheter at the start of the study. The bladder irrigation was done once a day, in the evening, for 3 consecutive days. The irrigation solution was NS (0.9%). The volume used in the irrigation was estimated on the basis of normal bladder capacity (400-600 cc) and normal